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PHYSIOLOGICAL STRESS DETECTOR DEVICE AND METHOD

Abstract:

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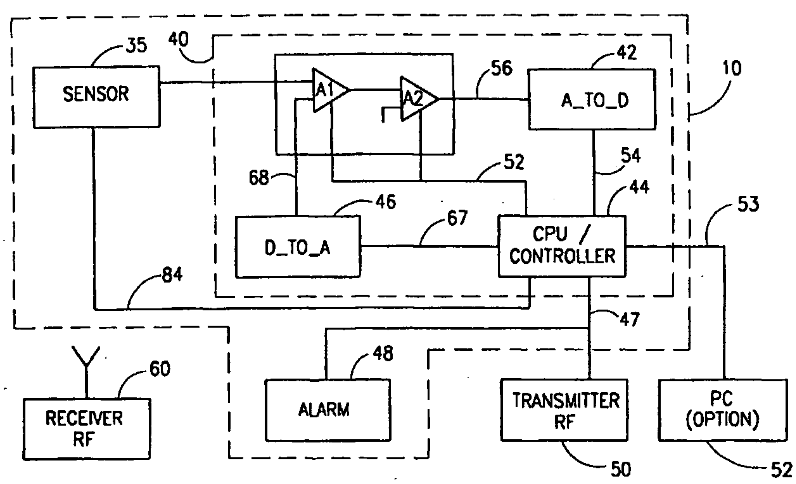

(57) Abstract

This invention is a method and device for measurement of a level of at least one blood constituent. The device includes a light source, and a light detector proximate the surface of an organ. The device also includes a pair of adjustable gain amplifiers (A1, A2), and a processor/controller (44) connected within a processing unit. The processing unit operates to separate an AC signal component from a DC signal component. The light source includes at least one light emitting unit. Preferably the light source alternatingly emits light at two different wavelength ranges, and normalizes the AC and DC output signals corresponding with the intensity of the light reflected from the organ and calculates a ratio of the normalized signals for each wavelength range. The device may determine the level of the blood constituent, and may also use this level for monitoring and/or to activate an alarm (48) when the level falls outside a predetermined range. The device, and the method may be applied to monitoring, inter alia, conditions of apnea, respiratory stress, reduced blood flow in organ regions, heart rate, jaundice, and blood flow velocity.

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PHYSIOLOGICAL STRESS DETECTOR DEVICE AND METHOD

FIELD OF THE INVENTION

The present invention relates to instruments which operate on the principle of pulse oximetry, in particular, to non-invasive hemoglobin saturation detectors and methods, and may be generally applied to other electro-optical methods of measuring blood constituents.

BACKGROUND OF THE INVENTION

Electro-optical measurement of blood characteristics has been found to be useful in many areas of blood constituent diagnostics, such as glucose levels, oxygen saturation, hematocrit, billirubin and others. This method is advantageous in that it can be performed in a non-invasive fashion. In particular, much research has been done on oximetry, a way of measuring oxygen saturation in the blood, as an early indicator of respiratory distress.

Infants during the first year of life are susceptible to breathing disturbances (apnea) and respiratory distress. Sudden Infant Death Syndrome (SIDS) is a medical condition in which an infant enters respiratory distress and stops breathing, leading to the death of the infant. Although the cause and warning signs of SIDS are not clear, it has been shown that early detection of respiratory distress can provide the time to administer the aid necessary to prevent death.

Many types of baby monitors are currently available, from simple motion detectors to complicated systems which stream oxygen enriched air into the

infant's environment. Some of the more accepted monitoring methods include chest motion monitors, carbon dioxide level monitors and heart rate (pulse) monitors. Unfortunately these methods often do not give the advance warning necessary for the caregivers to administer aid. In addition, these monitors are administered by attaching a series of straps and cords which are cumbersome to use and present a strangulation risk.

The chest motion monitor gives no warning when the breathing patterns become irregular or when hyperventilation is occurring, since the chest continues to move. Distress is only noted once the chest motion has ceased at which point there may only be a slight chance of resuscitation without brain damage. In addition these devices are known to have a high level of "false alarms" as they have no way to distinguish between the lapses in breathing which are normal for an infant (up to 20 seconds) and respiratory distress. These devices can cause excessive anxiety for the caregivers or cause them to ignore a signal which is true after responding repeatedly to false alarms.

Among other symptoms, SIDS causes an irregular heartbeat, resulting eventually in the cessation of heartbeat with the death of the infant. There are some instruments which use the EKG principle to monitor this clinical phenomenon. This is a limited method which has a very high rate of false positives since the monitors have inadequate algorithms to determine what is a SIDS event. Obviously, this is not a convenient method, nor is it desirable to have the infant constantly hooked up to an EKG monitor.

In light of these disadvantages a better method to use is a form of electro-optical measurement, such as pulse oximetry, which is a well-developed art. This method uses the difference in the absorption properties of oxyhemoglobin and deoxyhemoglobin to measure blood oxygen saturation in arterial blood. The oximeter passes light, usually red and infrared, through the body tissue and uses a photodetector to sense the absorption of light by the tissue. By measuring oxygen levels in the blood, one is able to detect respiratory distress at its onset giving sufficiently early warning to allow aid to be administered as necessary.

Two types of pulse oximetry are known. Until now, the more commonly used type has been transmission oximetry in which two or more wavelengths of light are transmitted through the tissue at a point where blood perfuses the tissue (i.e. a finger or earlobe) and a photodetector senses the absorption of light from the other side of the appendage. The light sources and sensors are mounted in a clip which attaches to the appendage and delivers data by cable to a processor. These clips are uncomfortable to wear for extended periods of time, as they must be tight enough to exclude external light sources. Additionally, the tightness of the clips can cause hematomas. Use of these clips is limited to the extremities where the geometry of the appendages is such that they can accommodate a clip of this type. The clip must be designed specifically for one appendage and cannot be used on a different one. Children are too active to wear these clips and consequently the accuracy of the reading suffers.

In another form of transmission oximetry, the light source and detector are placed on a ribbon, often made of rubber, which is wrapped around the appendage so that the source is on one side and the detector is on the other. This is commonly used with children. In this method error is high because movement can cause the detector to become misaligned with the light source.

It would be preferable to be able to use the other type of pulse oximetry known as reflective, or backscattering, oximetry, in which the light sources and light detector are placed side by side on the same tissue surface. When the light sources and detector can be placed on the tissue surface without necessitating a clip they can be applied to large surfaces such as the head, wrist or foot. In cases such as shock, when the blood is centralized away from the limbs, this is the way meaningful results can be obtained.

One difficulty in reflective oximetry is in adjusting the separation between the light source and the detector such that the desired variable signal component (AC) received is strong, since it is in the alternating current that information is received. The challenge is to separate the shunted, or coupled, signal which is the direct current (DC) signal component representing infiltration of external light from the AC signal bearing the desired information. This DC signal does not provide powerful information. If the DC signal component is not separated completely, when the AC signal is amplified any remaining DC component will be amplified with it, corrupting the results. Separating out the signal components is not a simple matter since the AC signal component is only 0.1% to 1% of the total

reflected light received by the detector. Many complicated solutions to this problem have been proposed.

If the light source and detector are moved further apart, this reduces the shunting problem (DC), however, it also weakens the already weak AC signal component. If the light source and detector are moved close together to increase the signal, the shunting (DC) will overpower the desired signal (AC).

Takatani et al., in US Pat. No. 4,867,557, Hirao et al., in US Pat. No. 5,057,695 and Mannheimer, in US Pat. No.5,524,617 all disclose reflective oximeters which require multiple emitters or detectors in order to better calculate the signal.

A number of attempts have been made to filter out the DC electronically (see Mendelson et al., in US Pat. No. 5,277,181). These methods are very sensitive to changes in signal level. The AC remaining after the filtering often contains a small portion of DC, which upon amplification of the AC becomes amplified as well, resulting in inaccurate readings. Therefore, this method is only useful in cases where the signal is strong and uniform.

Israeli patents 114082 and 114080 disclose a sensor designed to overcome the shunting problem by using optical fibers to filter out the undesired light. This is a complicated and expensive solution to the problem which requires a high level of technical skill to produce. In addition, it is ineffectual when the AC signal is relatively weak.

As can be seen from the above discussion, the prior art methods of addressing the AC/DC signal separation problem in reflective oximetry techniques

are complicated and expensive. Therefore, it would be desirable to provide a simple, low cost and effective method for achieving accurate reflective or transmissive oximetry detection of respiratory stress.

SUMMARY OF THE INVENTION

Accordingly, it is the broad object of the present invention to overcome the problems of separating the shunted light from the signal in order to provide a physiological stress detector which achieves accurate readings.

A general object of this invention is to overcome the problems of separating the shunted light from the signal in order to provide a respiratory stress detector which achieves accurate pulse oximetry readings for respiratory stress applications.

The present invention discloses a small, independent, sensor, for invasive and non-invasive applications unencumbered by cables or wires, which is capable of being attached to different body parts, to comfortably and accurately monitor blood constituent levels and the pulse of an infant or any other living organism. The apparatus may be applied to any part of the body without prior calibration. Accurate readings of blood constituent levels are obtained using the inventive method in which a precise separation of the AC and DC signal components has been achieved, allowing each signal component to be amplified separately. In order to accomplish this precise separation, the signal components are separated by a novel signal processing technique.

The inventive sensor may be adapted for many health monitoring situations including infant monitoring for SIDS, fetal monitoring, etc.

In a preferred embodiment adapted for SIDS, the sensor is designed to apply reflective oximetry techniques, so as to comfortably and accurately monitor the arterial oxygen levels and the pulse of an infant or any other living organism

prone to respiratory distress. This monitor is equipped with a processor capable of determining the need for an alarm and capable of signalling a distress signal to further alert to a crisis.

In another embodiment, in addition to the alarm being generated from the sensor itself, readings will be radio-transmitted to a base station, possibly at a nurse's station, to allow monitoring of the reading, and another alarm will be activated from the base station when the readings are outside of the accepted range.

In another preferred embodiment, the apparatus is mounted in a sock-type mounting such that the apparatus is properly applied when the sock is put on in the usual fashion. In addition, the sock-type apparatus blocks entrance of external light to the area of the sensor apparatus.

In yet another preferred embodiment, the apparatus is mounted on a ribbon-type mounting such that the apparatus is properly applied when the ribbon is tied around the head or other body part. In addition, the width of the ribbon is such that it will block entrance of external light to the area of the sensor apparatus. Additionally, the ribbon may be of dark color which also blocks entrance of external light to the area of the sensor apparatus.

In yet another preferred embodiment, the apparatus is mounted on a bracelet-type mounting such that the apparatus is properly applied when the bracelet is fastened to the wrist or other body part. In addition, the width of the bracelet is such that it blocks entrance of external light to the area of the sensor

apparatus. Additionally, the bracelet may be of dark color which also blocks entrance of external light to the area of the sensor apparatus.

There is therefore provided, in accordance with a preferred embodiment of the present invention, A non-invasive device disposed proximate the surface of an organ for measurement of a level of at least one blood constituent. The device includes: at least one light source, providing light directed toward the surface of the organ, the light being reflected from the organ, a light detector spaced apart from the at least one light source and being sensitive to intensity levels of the reflected light for producing intensity signals in accordance therewith, and a processing unit for processing the intensity signals received from the light detector. The processing unit includes: first and second amplifiers for amplifying the intensity signals, each in accordance with a respective first and second gain amplification factor, and a processor for automatically determining the first and second gain amplification factors in adjustable fashion. During a first stage, the first and second amplifiers amplify a DC signal component of the intensity signals in accordance with predetermined first and second gain amplification factors, the DC signal component is subtracted from the intensity signals at an input of the first amplifier, to isolate an AC signal component of the intensity signals. During a second stage, the second amplifier amplifies the isolated AC signal component in accordance with the adjustably-determined second gain amplification factor. The processing unit produces output signals in accordance with the isolated AC signal component

and the DC signal component and calculates in accordance therewith, at least one blood constituent level.

Furthermore, in accordance with another preferred embodiment of the present invention, the light source and the light detector of the device are held in a spaced relationship while in contact with the surface of the organ so as to substantially block entrance of external light therebetween.

Furthermore, in accordance with another preferred embodiment of the present invention, the processing unit further comprises: means for normalizing the AC and DC output signal components to produce first and second normalized signals, and means for forming a ratio of the first and second normalized signals. The processor calculates the blood constituent level in accordance with the ratio.

Furthermore, in accordance with another preferred embodiment of the present invention, the organ is the skin and the device is arranged for mounting on a ribbon, a bracelet and the like for placement on a part of a human or an animal body.

Furthermore, in accordance with another preferred embodiment of the present invention, the organ is the skin and the device is arranged for mounting on a tightly-fitted garment to be worn over a part of the body.

Furthermore, in accordance with another preferred embodiment of the present invention, the device further includes a transmitter for transmitting the

output signals to a receiver at a remote location, allowing monitoring of the at least one blood constituent level from the remote location. The receiver is equipped with an alarm unit for alerting when the at least one blood constituent level falls outside of a predetermined range.

Furthermore, in accordance with another preferred embodiment of the present invention, the processor develops a control signal when the adjustably-determined second gain amplification factor is established in the second stage, the signal is measured and the control signal shuts off the light source.

Furthermore, in accordance with another preferred embodiment of the present invention, the control signal conserves energy by reducing the operational duty cycle of the light source.

Furthermore, in accordance with another preferred embodiment of the present invention, the first and second gain amplification factors are determined by the processor in an iterative process by adjustably setting a gain amplification factor and measuring a dynamic voltage range of the output signals to determine if the voltage range falls within a predetermined window established by the processor.

Furthermore, in accordance with another preferred embodiment of the present invention, the light source comprises a single light emitting unit capable of controllably providing light having a wavelength range selected from at least a first wavelength range and a second wavelength range. The first wavelength

range is at least partially different from the second wavelength range. The single light emitting unit can be switched from emitting light within the first wavelength range to emitting light within the second wavelength range.

Furthermore, in accordance with another preferred embodiment of the present invention, the light source includes at least a first light emitting unit capable of controllably emitting light having a first wavelength range and a second light emitting unit capable of controllably emitting light having a second wavelength range. The first wavelength range is at least partially different from the second wavelength range.

Furthermore, in accordance with another preferred embodiment of the present invention, the light source provides light having wavelengths in the red and infrared ranges.

Furthermore, in accordance with another preferred embodiment of the present invention, the organ is the skin, the blood constituent is hemoglobin, and measurement of a level of oxygen saturation in the hemoglobin provides an early indication of respiratory stress.

Furthermore, in accordance with another preferred embodiment of the present invention, the respiratory stress is associated with Sudden Infant Death Syndrome.

Furthermore, in accordance with another preferred embodiment of the present invention, the device produces an output signal sent by the processor to

an alarm unit for alerting when the at least one blood constituent level falls outside of a predetermined range.

Furthermore, in accordance with another preferred embodiment of the present invention, the device is used to monitor the heart rate.

Furthermore, in accordance with another preferred embodiment of the present invention, the device is used as an apnea monitor.

Furthermore, in accordance with another preferred embodiment of the present invention, the device is a portable hand held reflective pulse oximeter.

Furthermore, in accordance with another preferred embodiment of the present invention, the device is adapted to determine blood billirubin levels.

Furthermore, in accordance with another preferred embodiment of the present invention, the device is adapted for mapping the intensity of the AC signal along the surface of the organ to detect regions of the organ having a reduced blood flow.

There is further provided, in accordance with another preferred embodiment of the present invention, a method for non-invasive measurement of a level of at least one blood constituent. The method includes the steps of: providing light from at least one light source disposed proximate the skin, directing the light toward the skin surface, the light being reflected from the skin, providing a light detector spaced apart from the light source and being sensitive to intensity levels of the light reflected from the skin for producing intensity

signals in accordance therewith, and processing the intensity signals received from the light detector. The processing step includes the steps of amplifying the intensity signals in first and second amplifiers, each in accordance with a respective first and second gain amplification factor, and automatically determining the first and second gain amplification factors in adjustable fashion. During a first stage, the first and second amplifier amplify a DC signal component of the intensity signals in accordance with predetermined first and second gain amplification factors, the DC signal component being subtracted from the intensity signals at an input of the first amplifier, thereby isolating an AC signal component of the intensity signals. During a second stage, the second amplifier amplifies the isolated AC signal component in accordance with the adjustably-determined second gain amplification factor. The processing step produces output signals in accordance with the isolated AC signal component and the DC signal component and calculates in accordance therewith, the at least one blood constituent level.

Furthermore, in accordance with another preferred embodiment of the present invention, the method further includes the step of transmitting the output signals to a receiver at a remote location, allowing monitoring of the at least one blood constituent level from the remote location. The receiver is equipped with an alarm unit for alerting when the at least one blood constituent level falls outside of a predetermined range.

Furthermore, in accordance with another preferred embodiment of the present invention, the step of processing further includes normalizing the AC and DC output signal components to produce first and second normalized signals, forming a ratio of the first and second normalized signals, and calculating the blood constituent level in accordance with the ratio.

Furthermore, in accordance with another preferred embodiment of the present invention, the method further includes the steps of developing a control signal when the adjustably-determined second gain amplification factor is established in the second stage,

measuring the signal and shutting off the light source in response to the control signal.

Furthermore, in accordance with another preferred embodiment of the present invention, the method further includes the steps of determining the first and second gain amplification factors by a processor in an iterative process by adjustably setting a gain amplification factor, and measuring a dynamic voltage range of the output signals to determine if the voltage range falls within a predetermined window established by the processor.

Furthermore, in accordance with another preferred embodiment of the present invention, the blood constituent is hemoglobin, the method further includes the step of measuring a level of oxygen saturation in the hemoglobin providing an early indication of respiratory stress.

Furthermore, in accordance with another preferred embodiment of the present invention, the respiratory stress is associated with Sudden Infant Death Syndrome.

Furthermore, in accordance with another preferred embodiment of the present invention, the method further includes the step of initiating an alarm for alerting when the blood constituent level falls outside of a predetermined range.

Furthermore, in accordance with another preferred embodiment of the present invention, the alarm is selected from an audible alarm, a visual alarm, a tactile alarm, dialing a telephone number and any combination thereof.

Furthermore, in accordance with another preferred embodiment of the present invention, the light is alternatingly selected from at least a first wavelength range and a second wavelength range. The first wavelength range is at least partially different from the second wavelength range.

Furthermore, in accordance with another preferred embodiment of the present invention, the first wavelength range includes wavelength of red light and the second wavelength range includes wavelength of infra-red light, the blood constituent is hemoglobin and the method determines the level of oxygen saturation of the hemoglobin.

Furthermore, in accordance with another preferred embodiment of the present invention, the method is used for monitoring the heart rate.

Furthermore, in accordance with another preferred embodiment of the present invention, the method is used for monitoring a condition of apnea.

Furthermore, in accordance with another preferred embodiment of the present invention, the method is used for monitoring the level of billirubin in blood.

Furthermore, in accordance with another preferred embodiment of the present invention. The method further includes the step of repeating the steps of providing light, providing a light detector and processing at a plurality of positions along the skin for mapping the levels of the AC signal component along the surface of the skin to detect regions of reduced blood flow.

There is still further provided, in accordance with another preferred embodiment of the present invention, a method for measurement of a level of at least one blood constituent. The method includes the steps of providing light from at least one light source disposed proximate the surface of an organ, directing the light toward the surface of the organ, the light being reflected from the organ, providing a light detector spaced apart from the light source. The light detector is sensitive to intensity levels of the light reflected from the organ for producing intensity signals in accordance therewith, and processing the intensity signals received from the light detector. The processing step includes the steps of amplifying the intensity signals in first and second amplifiers, each in accordance with a respective first and second gain amplification factor, and automatically determining the first and second gain amplification factors in

adjustable fashion. During a first stage, the first and second amplifier amplify a DC signal component of the intensity signals in accordance with predetermined first and second gain amplification factors, the DC signal component is subtracted from the intensity signals at an input of the first amplifier, thereby isolating an AC signal component of the intensity signals. During a second stage, the second amplifier amplifies the isolated AC signal component in accordance with the adjustably-determined second gain amplification factor. The processing step produces output signals in accordance with the isolated AC signal component and the DC signal component, and calculating in accordance therewith, the blood constituent level.

Furthermore, in accordance with another preferred embodiment of the present invention, the organ is an internal organ and the method further includes the step of repeating the steps of providing light, providing a light detector, and processing, at a plurality of positions along the surface of the internal organ for mapping the levels of the AC signal component along the surface of the internal organ to detect regions of reduced blood flow.

There is also provided, in accordance with another preferred embodiment of the present invention, a method for non-invasively determining the blood flow velocity in a region of an organ. The method includes the steps of positioning a first pulse-oximetry device and a second pulse-oximetry device proximate the surface of the region. The first and the second device are separated from each other by a predetermined distance, simultaneously obtaining a first and a

second sets of data representing the pulsatile variation at the locations of the first and the second device, respectively, as a function of time, each of the first set and the second set of data includes at least one extremum data value, the extremum data value of the first set of data corresponds to the extremum data value of the second set of data, calculating the time interval between the extremum data value of the first set of data and the extremum data value of the second set of data, dividing the value of the predetermined distance by the value of the time interval to obtain a value representing the approximate blood flow velocity in the region of the organ, wherein each of the first device and the second device includes at least one light source, providing light directed toward the surface of the organ, the light being reflected from the organ, a light detector spaced apart from the at least one light source and being sensitive to intensity levels of the reflected light for producing intensity signals in accordance therewith, and a processing unit for processing the intensity signals received from the light detector. The processing unit includes first and second amplifiers for amplifying the intensity signals, each in accordance with a respective first and second gain amplification factor, and a processor for automatically determining the first and second gain amplification factors in adjustable fashion. During a first stage, the first and second amplifiers amplify a DC signal component of the intensity signals in accordance with predetermined first and second gain amplification factors, the amplified DC signal component being subtracted from the intensity signals at an input of the first amplifier, to isolate an AC signal component of the intensity signals. During a second stage, the

second amplifier amplifies the isolated AC signal component in accordance with the adjustably-determined second gain amplification factor. The processing unit produces output signals in accordance with the isolated AC signal component and the DC signal component and calculates in accordance therewith.

Furthermore, in accordance with another preferred embodiment of the present invention, the organ is the skin.

Finally, in accordance with another preferred embodiment of the present invention, the extremum data value is selected from a minimum data value and a maximum data value.

Other features and advantages of he invention will become apparent from the following drawings and description.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding, the invention will now be described, by way of example only, with reference to the accompanying drawings in which like numerals designate like components throughout the application, and in which:

Fig. 1 is a schematic layout diagram of a physiological stress detector device, constructed and operated in accordance with the principles of the present invention;

Fig. 2 is an electronic schematic diagram of a prior art signal processing technique, for use with the device of Fig. 1;

Figs. 3a- 3b show, respectively, a prior art signal waveform representing emitted and received light;

Figs. 4 and 5a-b show, respectively, arrangements for wearing the device of Fig. 1 on the body of an infant on a leg, foot or head;

Fig. 6 is an electronic block diagram showing the signal processing components of the device ofthe present invention;

Fig. 7 is an algorithm of a signal processing technique performed in accordance with the principles of the present invention;

Figs. 8a-b are, respectively, signal waveforms representing emitted red and infrared light used in the device of Fig. 1;

Fig. 9 is a timing diagram applied in an automatic gain adjustment procedure during signal processing;

Fig. 10 is a schematic illustration of a device for determining blood flow velocity in accordance with another preferred embodiment of the present invention; and

Fig. 11 is a schematic graph useful in understanding the method of determining blood flow velocity used by the device of Fig. 10.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The following description presents a detailed construction of a physiological stress detector device adapted for use in monitoring arterial oxygen levels. In this particular application, the reflective oximetry method uses light wavelengths in the red and infrared ranges, since these are most suitable for detecting oxygen saturation in hemoglobin. As will be understood by those skilled in the art, particular design features used for this application can be varied for different applications. For example, in an application for monitoring jaundice through bilirubin levels, other suitable, light wavelengths would be used. Therefore, the light wavelengths discussed in the following description are not intended to limit the scope of the present invention, and are to be understood as pertaining to the subject example only.

Referring now to Fig. 1, there is shown a preferred embodiment of a physiological stress detector device 10 constructed and operated in accordance with the principles of the present invention. Device 10 comprises a housing 12 arranged for placement in close proximity to a skin surface 14. Housing 12 may be provided as a casing enclosing a light source 16 emitting two wavelengths, red and infrared, and a photodetector 18 spaced apart from the light source 16. Device 10 is designed to be operated such that when light source 16 emits light of a red or infrared wavelength, the light penetrates skin tissue (arrow A) and a portion of the light is reflected back to light detector 18, along a path defined by line 20.

The light source 16 may be implemented as a single component which can controllably emits red or infrared light. A non limiting example of the light source 16 is the selectable wavelength light emitting diode (LED) component model L122R6IR880, or for pediatric or prematurely born baby applications the component model SML12R6IR880, both components are commercially available from Ledtronics, CA, U.S.A. However, The light source 16 may also include two separate suitable light sources. For example, the light source 16 may include two separate light sources (not shown) such as an LED emitting red light and another different LED emitting infrared light.

It is noted that, while, preferably, the light source 16 includes one or more LEDs emitting in the suitable red and infrared ranges, other light sources may be used such as incandescent lamps in combination with suitable optical filters, various types of gas discharge or arc lamps, with or without optical filters, diode laser devices, or any other.

For the pulse-oximetry application the light detector 18 may be a photodiode, such as the model BPW34 photodiode, or for pediatric and premature born babies the model BPW34S photodiode, both commercially available from Siemens Semiconductor Group, Germany. However, many other types of photo-detecting devices may be used such as resistive photocells, or any other type of photodetector which has the required sensitivity at the wavelengths used for the specific application of the device 10.

It is noted that the device 10 of Fig. 1 also includes further electronic components (not shown in Fig. 1) which are disclosed in detail hereinbelow (as best seen in Fig. 6).

As described in the background of the invention, the device 10 employs non-invasive reflective oximetry techniques to provide measurement of blood characteristics useful in diagnostic procedures and detection of physiological stress. As mentioned, one difficulty in reflective oximetry is in adjusting the separation between light source 16 and detector 18 such that the desired signal received by light detector 18 is strong and not affected by shunted, or coupled, light from source 16. Figs. 2 and 3a-3b illustrate this problem and the prior art techniques currently available for its solution.

In Fig. 2 there is shown an electronic schematic diagram of a signal processing filter 22 used to separate the variable signal (AC) component of received light from the shunted (DC), or coupled, light. The separation is achieved by a blocking capacitor 24 on the input of an operational amplifier 26 used to amplify the variable signal portion. The DC signal component of the received light, which does not pass through blocking capacitor 24, forms the input of, and is amplified by operational amplifier 28.

As illustrated in Figs 3a-3b, the signal waveform representing the emitted light, (Fig. 3a) is substantially reproduced as a received signal waveform (Fig. 3b). Even after filtering by signal processing filter 22, the AC signal component remaining ΔSIG is only a small portion of a larger signal which has been amplified by operational amplifier 26, and therefore dominates the variable

signal portion. Thus, this method of signal separation results in inaccurate readings of reflected light, and cannot provide accurate information in oximetry measurements.

In Figs. 4 and 5a-b there are shown alternative configurations of device 10, respectively, provided in a foot bracelet 30, a sock 32 worn around the ankle, and a ribbon 34 worn around the head. In each arrangement, casing 12 is designed to be held tightly against skin surface 14 to reduce the amount of stray light entering into the optical path between light source 16 and detector 18.

Preferably, the casing 12 is made from a material opaque to light in the relevant spectral range to which the detector 18 is sensitive, such as an opaque plastic material, metal or the like. The foot bracelet 30, the sock 32 and the ribbon 34 may be made of a material which allows the casing 12 to be tightly pressed against the skin. This material may be a flexible material such as a flexible fabric. The material may also be a porous or woven material to prevent excessive perspiration of the skin thereunder.

Referring now to Fig. 6 , there is shown an electronic schematic block diagram of device 10. Device 10 comprises a sensor 35 incorporating light source 16 and detector 18. The sensor 35 may also include a preamplifier circuit (not shown) for amplifying the output signals of the detector 18 and feeding the amplified signals to the processing unit 40. It will be appreciated by those skilled in the art that the numbers of light sources and detectors can be varied while keeping the same processing method. In addition, device 10 comprises a signal processing unit 40 including a pair of operational amplifiers A1 and A2, an analog

to digital converter 42, a central processing unit (CPU)/controller 44, and a digital to analog converter 46. In critical applications, such as SIDS, when there exists a need for emergency first aid availability, when CPU 44 has determined that the value obtained is not within the acceptable range an output signal 47 is fed to an alarm unit 48 causing an alarm to be activated. Optional connections to an RF transmitter 50 and PC computer 52 are available. Sensor 35 is designed to be powered by a small battery (not shown).

According to another embodiment of the present invention, processing unit 40 with or without alarm 48, RF transmittor 50 and/or PC 52 are connected to the sensor 35 via a cable or by wireless transition. In this case sensor 35 does not require a battery.

It is noted that, the alarm unit 48 may activate a visual alarm, an audio alarm, a tactile alarm (such as a vibratory signal), or an audio-visual alarm. The alarm unit 48 may also initiate the automatic dialing of a telephone number and may also activate any combination of any of the above types of alarms, or of other types of alarms.

The coupling of operational amplifiers A1 and A2 is between the output of amplifier A1 and the input of amplifier A2. The gain amplification factor of each amplifier is set by the central processing unit 44 via a signal in accordance with an automatic adjustable gain technique described further herein. Analog to digital converter 42 provides a digital input signal 54 based on the level of output signal 56 from amplifier A2. The central processing unit 44 is programmed to process the information contained in input signal 54, and thereby determine blood oxygen

saturation levels detected by sensor 35. The output signal 47 from CPU 44 may be used to trigger alarm 48, or its information can be transmitted by an RF transmitter 50 to a receiver 60 for remote station processing. Data analysis can be performed by PC 52 based on a data output signal 53.

Based on the block diagram of Fig. 6, device 10 can be constructed in accordance with state of the art electronic design techniques employing, for example a 8051 micro-controller, commercially available from Intel Corp, U.S.A., or any other suitable processor or controller to implement the CPU/controller 44.

The properties of amplifiers A1 and A2 are selected in accordance with electronic design rules well known in the art. In a non-limiting example, amplifier A1 is the model PGA205AU programmable gain instrumentation amplifier, and amplifier A2 is the model PGA204AU programmable gain instrumentation amplifier, commercially available from Burr-Brown, AZ, U.S.A. However, the amplifiers A1 and A2 may be any other suitable type of amplifier. For example, while in the preferred embodiment disclosed hereinabove each of the amplifiers A1 and A2 is shown as an operational amplifier unit, each of the amplifiers A1 and A2 may be implemented as a multi-stage amplifier device containing more than one amplification stages.

As mentioned in the background of the invention, problems with prior art reflective oximetry techniques are related to the measurement of the AC signal component which forms a small part of the larger DC signal component provided by light sensor 35. Whereas the previous techniques involved use of a blocking capacitor 24 as described in Figs. 2 and 3a-3b, the present invention provides a

novel solution to the signal amplification problem such that more accurate oximetry measurement may be obtained.

It is noted that, depending on the specific detector used, the AC and DC signal components generated by the detector 18 may be current or voltage AC and DC signal components, and that the terms AC signal component and DC signal component throughout the specification and claims define AC and DC components of the output signal of the detector 18 and may include voltage signal components and current signal components. However, the AC and DC signal components may also include any other type of electrical or photonic (optical) signal which may be the output of any suitable detector type useful with the device of the present invention.

In accordance with the principles of the present invention, processing unit 40 applies a novel technique for separating the AC signal component from the DC signal component. The steps carried out by CPU 44 in this technique are illustrated in the flow chart of Fig 7.

In start block 62, CPU 44 begins its operation by initializing the gain of analog amplifiers A1 and A2 automatically. In block 64 the detected signal from sensor 35 is measured, and this is performed by providing output signal 56 from signal processing unit 40 to the analog to digital converter 42, so that it is converted to a digital input signal 54 for input to CPU 44. In block 66, CPU 44 calculates the DC signal component of the detected signal. This is achieved by a two-stage process.

In the first stage, output signal 56 is treated as a pure DC signal, such that CPU 44 takes the average of this signal level, and generates a digital output signal 67 which is converted by the digital to analog converter 46 to an analog reference shift signal 68. In block 70, reference shift signal 68 is fed into the negative input of amplifier A1 and amplifier A1 effectively neutralizes the DC component by applying reference shift signal 68 against the detected signal from sensor 35. This produces a null output for input to amplifier A2.

In the second stage, in block 72, amplifier A2 receives the AC signal component of the detected signal and amplifies it, thereby producing an output signal 56 containing information based on the reflective oximetry technique. This information, when converted to a digital signal in analog to digital converter 42, provides digital input signal 54 to CPU 44. In block 74, the oximetry calculation is performed by the CPU/controller 44 based on measurements derived from sensor 35, in accordance with the information provided by digital input signal 54. The results of the oximetry calculation are provided as output signal 47 or in the form of a data signal 35 fed to a PC computer 52. Output signal 47 may be used to activate an alarm 48 or it may be provided as the signal for transmission via RF transmitter 50 to a remote receiver 60, to allow base station monitoring of the reading.

Referring now to Figs. 8a-b, there are shown respectively, pulse signal waveforms representing light received in the red and infrared ranges by light detector 18 in sensor 35. Light is provided by light source 16 in pulses each having, for example, a duration of 1.6 milliseconds and a period of 15.6

milliseconds. The analysis of a typical light pulse is provided in Fig. 9, showing the time scale division of the 1.6 millisecond pulse into two cyclical gain adjustment periods 76 and 78, respectively. The red and infrared pulses are staggered so as to minimize interference between them.

In Fig. 9, a time division scale is developed in which each of the pulsed light waveforms is divided into two periods 76 and 78, each having, for example, a maximum duration of 800 microseconds, during which the gain amplification factor is set for each of operational amplifiers A1 and A2. The first period is used to set the gain for and measure the DC signal component, and the second period is used to set the gain for and measure the AC signal component.

The gain amplification factor is automatically adjusted in an iterative process. After a predetermined delay, for example 50 microseconds, the gain amplification factor is set during interval 80, and the output signal 56 of signal processing unit 40 is measured to determine if it falls within the window defined by CPU 44. For example, a dynamic voltage range of between 0.4-4 volts is established by CPU 44, and output signal 56 is measured during interval 82, to see if it falls within this window. If it does, the gain amplification factor is fixed at its current value. If, on the other hand, output signal 56 does not fall within this window, another setting is provided by CPU 44 and again the output signal 56 is measured. This process is repeated, in iterative fashion, within the first period of the cyclical gain adjustment procedure until the output signal 56 falls within the desired window.

If the desired window for the DC signal component is obtained before the 800 microseconds of the first period has elapsed, the first period is shortened accordingly, and the second period is commenced, during which the same procedure is performed for the AC signal component. Once a desirable window is attained for the AC signal component, the second period may be shortened accordingly, and CPU 44 sends a control signal 84 to sensor 35, to shut off the light source for that pulse. In this fashion, an energy savings is achieved by reducing the duty cycle of light source 16, and reducing the current drain from the battery and extending its useful life. Control signal 84 is provided for each individual light pulse, so that the maximum energy savings is achieved. If the 800 microseconds has elapsed without establishing the gain amplification factor, the signal is ignored.

It is noted that, the values disclosed hereinabove for the pulse duration and pulse interval of Figs. 8a and 8b and for the two periods 76 and 78 of Fig. 9 are given as a non-limiting example only and may be replaced by other suitable values depending, *inter alia*, on the available electronic component speed, the processing speed of the processor/controller 44 and the specific application type. For example, the pulse duration and pulse interval of Figs. 8a and 8b can have the values of 0.6 milliseconds and 15.6 milliseconds, respectively, and the two periods 76 and 78 of Fig. 9 may each have the value of 300 microseconds.

It is further noted that, while in the embodiment disclosed hereinabove (Figs. 8a, 8b and 9) a DC gain correction procedure is performed for each first time period 76 as disclosed in detail hereinabove, it was found that the DC

correction can be performed much less often with no deterioration of the devices performance and in some cases with a resulting improvement of measurement stability. For example, if a typical measurement cycle lasts approximately 4-5 seconds, in order to include a few heart pulse cycles, and includes 256 infrared and red light measurement periods (each of the light measurement periods comprising the time periods 76 and 78), performing the DC correction procedure only once for every 256 measurement periods (i.e once for each measurement cycle) results with a better stability. Thus, the number of times of performing the DC correction procedure of the present invention per measurement cycle may be varied for optimizing the stability and accuracy of the measurements. The optimal number of times of performing the DC correction procedure of the present invention per measurement cycle may depend, *inter alia*, on the optical parameters of the light source 16 and the detector 18 of the device 10 and on the specific wavelengths implemented in the specific application.

An advantage of reducing the number of DC corrections per measurement cycle is that it reduces the computational load of the CPU 44, enabling increasing the number of light measurement time periods within each given measurement cycle or, alternatively, using a less powerful CPU 44 to reduce the overall cost of the device 10 while conserving or even improving the accuracy and stability of the measurements.

The gain amplification factors are selected from a set of preselected values. Amplifier A1, which acts to amplify the DC signal component, can have

gain amplification factors of 1, 2, 4 or 8. Amplifier A2, which amplifies the AC signal component, operates in the amplification ranges of 1, 10, 100 or 1000.

An advantage of the ability to automatically switch between the gain amplification factors based on the iterative process performed by CPU 44, is that it allows the device 10 to obtain oximetry measurements in different parts of the body without recalibrating the gain amplification factor for each area.

The separated AC and DC signals are calibrated using the formulas:

$$V_{AC} = \frac{(V_{a/d})\,K}{A_{AC} * A_{DC}}$$

$$V_{DC} = \frac{V_{DC} = (V_{a/d})\,K}{A_{AC} * A_{DC}}$$

where $V_{a/d}$ is the signal from the analog to digital converter and A_{AC} and A_{DC} represent the gain of the A2 and A1 amplifiers, respectively. Using these calibration equations it is possible to calculate a value for each of the signal components (V_{AC} and V_{DC}) which is substantially separated from the other signal component.

Once the AC and DC signal components are calibrated, calculations for purposes of determining oxygen saturation are performed by taking the AC and DC values for each wavelength and forming a ratio:

$$G = \frac{V(AC)_{red}/V(DC)_{red}}{V(AC)_{infrared}/V(DC)_{infrared}}$$

This ratio is used to calculate the oxygen saturation in the formula:

$SatO_2 = B - A * G$

where B and A are constants. CPU 44 determines whether or not this value falls within the desired window, and in cases where the value is unacceptable and stress is detected, an output signal 47 is sent to alarm 48 and the alarm willturn on. Alternatively, or in addition, the output signal 47 can be sent to RF transmitter 50 for transmission to receiver 60. Additional information, such as a log of all readings, may be sent from CPU 44 as a data output signal 53 to PC 52.

In summary, the physiological stress detector device of the present invention provides a non-invasive method for more accurately measuring blood constituents in a compact, easily utilized design. It is especially useful for application in SIDS monitoring systems due to its compact light weight design which is provided with no cumbersome, dangerous cable connections.

An advantage of the devices and methods of the present invention is that the sensitivity and improved signal to noise ratio of the present method enables use of transmissive methods of pulse oximetry under conditions where

the signals are of low amplitude relative to the noises. In a non-limiting example, the method and devices may be particularly useful for transmissive oximetry under conditions of low blood perfusion such as in systemically shocked patients or in cases of severe hypothermia.

A major advantage of the present invention is in its application to reflective oximetry where the signals are usually of a relatively low amplitude. In particular, the sensitivity of the method and the devices may enable performing reflective pulse oximetry on regions of the body which exhibit particularly low amplitude signals such as the wrist region, or the ankle region of adults and babies.

Reference is now made to Fig. 10 which is a schematic illustration of a device 90 for determining blood flow velocity in accordance with another preferred embodiment of the present invention.

The device 90 includes a housing 92 and two pulse oximetry devices 10a and 10b attached thereto. The devices 10a and 10b are constructed as the device 10 disclosed hereinabove and are simultaneously operated to provide an amplified pulse oximetry AC signal as disclosed in detail for the device 10 hereinabove. The fixed distance D between the device 10a and the device 10b is represented by the double headed arrow labeled D. The device 90 is placed on a region of skin A and the pulse oximetry AC signal is simultaneously determined for each of the devices 10a and 10b.

Reference is now made to Fig. 11 which is a schematic graph useful in understanding the method of determining blood flow velocity used by the device

90 of Fig. 10. The horizontal axis represents time and the vertical axis represents the amplitude of the reflective oximetry AC signals. The curve 94A represents the AC signal output from the device 10a and the curve 94B represents the AC signal output from the device 10b. The minima 96A and 96B of the curves 94A and 94B, respectively represent the minima of the reflected AC signal due to the pulsation of the blood flow. The time delay ΔT between the reflection minima 96A and 96B represent the time delay between the registration of a minimum reflectance by the device 10a and its registration by the device 10b. The delay results from the finite blood velocity and the distance D separating the devices. Since the distance D between the devices 10a and 10b is known, the approximate blood flow velocity V can be determined by calculating the value

$$V = D/\Delta T.$$

The processing unit 40 of one of the devices 10a or 10b thus acquires two data sets. The first data set represents the AC signal component of the device 10a and the second data set represents the AC signal component of the device 10b. Preferably, both of the data sets are digital data sets and are sampled simultaneously. The data sets are sampled such that each data set includes at least one extremum data value corresponding to a minimum or a maximum value of the AC signal component, the processing unit 40 detects the extremum point for each of the data sets using any method known in the art for detecting an extremum point. The processing unit then calculates the time interval ΔT between the corresponding extremum points of the first and the second data sets and calculates the blood flow velocity from the ratio $\Delta T/D$.

Preferably, for devices using reflective pulse oximetry of the present invention, the extremum data values used are minimum values representing minimal values of reflected light due to maximal absorption of the light from the light sources 16 of the devices 10a and 10b. However, the extremum values may also be maxima. For example, in an embodiment where transmissive pulse oximetry devices are used, the extremum values may be maxima.

It is noted that, while each of the devices 10a and 10b may have a CPU 44 as disclosed hereinabove, in accordance with another preferred embodiment of the present invention, the device 90 may include a single CPU unit (not shown) which may be shared for performing all the calculations and control functions disclosed hereinabove for the operation of each of the devices 10a and 10b and for additionally performing the determination of ΔT and the calculation of the approximate blood flow velocity therefrom.

It will be appreciated by those skilled in the art that suitable methods for detecting and timing the reflection minima 96A and 96B are well known in the art and are not included in the subject matter of the present invention, and will therefore not be described herein in detail.

It is noted that while the device and method for determining blood flow velocity disclosed hereinabove is adapted for use with a pair of devices 10a and 10b, a larger number of devices (not shown) may be used together either as a multiplicity of device pairs or in any other geometrical configuration for improving the accuracy of the measurement by averaging the results of multiple pair determinations or by any other suitable computational method known in the art.

It is noted that, while the preferred embodiments of the present invention are particularly adapted for reflective pulse oximetry applications, it may be also implemented in many other applications. For example, the method and the device of the present invention may be adapted to the monitor bilirubin levels for the detection and monitoring of jaundice, by suitably selecting a light source which emits wavelengths of light in the range selectively absorbed by bilirubin, (approximately between 400 - 600 nanometer).

In another example, the present invention may also be used to detect and monitor blood constituents which have distinct absorbance peaks in the visible range, the near ultraviolet (UV) range or in both the visible and the near UV range. For this type of applications one or more of the light wavelengths used may be obtained from a gas discharge lamp or from any another suitable source of light in the near UV range.

Another application of the present invention is the application of the method for the determination and mapping of areas of organs suspected of a reduced blood flow due to chronic or temporary clinical condition. For example if an internal or external organ is suspected to have developed gangrene the device 10 of the present invention may be used to map areas having low or reduced blood flow by moving the device 10 along the organ and in contact therewith and mapping areas of reduced blood flow by recording and mapping the amplitude of the minima of the pulse oximetry AC component as disclosed hereinabove along the surface of the organ. This method may be particularly useful in mapping of such reduced flow areas in cases where regular transmissive pulse oximetry is

not applicable due to inaccessibility problems or due to very noisy signal conditions.

One exemplary application is mapping the external surface of the intestines using a small pre-sterilized reflective oximetry device such as the device 10 of the present invention. In such a case transmissive oximetry devices cannot be used because it is not possible to position a light source and a light detector on opposite sides of the intestinal wall. The device 10 is particularly advantageous here because it can be simply moved along the external surface of the suspected intestinal part and because of its improved sensitivity and reduced noise level.

The above mapping method may be applied to many other organs such as limbs suspected of blood flow disturbances due to a gangrene condition or other diseases.

It is noted that the devices of the present invention may be implemented in a variety of different configurations. The devices 10 or 90 of Figs. 1 and 10, respectively may be connected to a computer (not shown) or a monitor (not shown). The computer or monitor may include a display device (not shown).

An alternative configuration may include the device 10, connected to a housing(not shown) wirelessly or by suitable wires. The housing may also include a liquid crystal display device (LCD), such as the LCD display model G1216001N000-3D0E, commercially available from Seiko Instruments Inc., Japan, suitably connected to the CPU 44 for displaying alphanumeric symbols representative of one ore more parameters of the pulse oximetry signal such as

the pulse frequency , or amplitude or any other data. The LCD display may also display the AC signal graphically with or without the alphanumeric data.

In a third configuration of the device of the present invention the pulse oximetry device includes all the optical and electronic components within one single device shaped as a wrist watch like device to be worn as a self contained unit. One non-limiting example (not shown) is a device worn on the wrist and shaped like a wrist watch. All the components of the device 10 are integrated within the device such that the light source 16 and the detector 18 are attached to the device so as to be in contact with the skin when the device is worn. All the necessary electronic components disclosed hereinabove are also integrated in the device including a power source such as a battery. The device may thus monitor signals, may or may not collect and store data and may or may not activate an alarm unit or transmit a distress signal as disclosed hereinabove in detail. It is noted that this self contained integrated device configuration may also be shaped to be placed in contact with the skin on the limbs, forehead or any other organ of the patient by suitable means such as strips bands of flexible material, adhesives or any other suitable attachment means known in the art.

The self contained integrated device configurations may be used for a variety of applications. For example, in a preferred embodiment of the present invention, the device may determine the pulse rate of the wearer. It is known that during a meal the pulse rate increases. The pulse rate may thus be used for diet control by reporting to the user when the pulse rate reaches a predetermined value or when the increase in the pulse rate following the beginning of a meal is

within a predetermined rate. The user may thus use the device for obtaining an indication of when to stop consuming food.

The device may also be used for radial pulse measurement in cardiac measurements and for various bio-feedback application.

In all of the above applications of the self contained integrated device configurations, such as a bracelet-like device or the like the device has an advantage of being a compact, lightweight and convenient wearable device while still providing the high sensitivity, accuracy and relative immunity to movement artifacts of the present invention.

It is noted that the devices of the present invention, as used in the various applications disclosed herein above, may also be configured and used as monitoring devices in a hospital environment, as well as for domestic use.

It is further noted that the devices and methods of the present invention may be adapted for use of humans and animals.

Having described the invention with regard to certain specific embodiments thereof, it is to be understood that the description is not meant as a limitation, since further modifications will now become apparent to those skilled in the art, and it is intended to cover such modifications as fall within the scope of the appended claims.

CLAIMS

1. A non-invasive device disposed proximate the surface of an organ for measurement of a level of at least one blood constituent, comprising:

at least one light source, providing light directed toward said surface of said organ, the light being reflected from said organ;

a light detector spaced apart from said at least one light source and being sensitive to intensity levels of said reflected light for producing intensity signals in accordance therewith; and

a processing unit for processing said intensity signals received from said light detector, said processing unit comprising:

first and second amplifiers for amplifying said intensity signals, each in accordance with a respective first and second gain amplification factor; and

a processor for automatically determining said first and second gain amplification factors in adjustable fashion;

wherein during a first stage, said first and second amplifiers amplify a DC signal component of said intensity signals in accordance with predetermined first and second gain amplification factors, said amplified DC signal component being subtracted from said intensity signals at an input of said first amplifier, to isolate an AC signal component of said intensity signals,

and wherein during a second stage, said second amplifier amplifies said isolated AC signal component in accordance with said adjustably-determined second gain amplification factor,

said processing unit producing output signals in accordance with said isolated AC signal component and said DC signal component and calculating in accordance therewith, at least one blood constituent level.

2. The device according to claim 1 wherein said at least one light source and said light detector are held in a spaced relationship while in contact with the surface of said organ so as to substantially block entrance of external light therebetween.

3. The device according to claim 1 wherein said processing unit further comprises:

means for normalizing said AC and DC output signal components to produce first and second normalized signals; and

means for forming a ratio of said first and second normalized signals,

said processor calculating said blood constituent level in accordance with said ratio.

4. The device according to claim 1 wherein said organ is the skin and said device is arranged for mounting on a ribbon, a bracelet and the like for placement on a part of a human or an animal body.

5. The device according to claim 1 wherein said organ is the skin and said device is arranged for mounting on a tightly-fitted garment to be worn over a part of the body.

6. The device according to claim 1 further comprising a transmitter for transmitting said output signals to a receiver at a remote location, allowing monitoring of said at least one blood constituent level from said remote location,

said receiver being equipped with an alarm unit for alerting when said at least one blood constituent level falls outside of a predetermined range.

7. The device according to claim 1 wherein said processor develops a control signal when said adjustably-determined second gain amplification factor is established in said second stage, said signal being measured and said control signal shutting off said light source.

8. The device according to claim 7 wherein said control signal conserves energy by reducing the operational duty cycle of said at least one light source.

9. The device according to claim 1 wherein said first and second gain amplification factors are determined by said processor in an iterative process by adjustably setting a gain amplification factor and measuring a dynamic voltage range of said output signals to determine if said voltage range falls within a predetermined window established by said processor.

10. The device according to claim 1 wherein said at least one light source comprises a single light emitting unit capable of controllably providing light having a wavelength range selected from at least a first wavelength range and a second wavelength range, said first wavelength range being at least partially different from said second wavelength range, said single light emitting unit can be switched from emitting light within said first wavelength range to emitting light within said second wavelength range.

11. The device according to claim 1 wherein said light source comprises at least a first light emitting unit capable of controllably emitting light having a first wavelength range and a second light emitting unit capable of controllably emitting light having a second wavelength range, said first wavelength range being at least partially different from said second wavelength range.

12. The device according to claim 1 wherein said at least one light source provides light having wavelengths in the red and infrared ranges.

13. The device according to claim 12 wherein said organ is the skin, said blood constituent is hemoglobin, and wherein measurement of a level of

oxygen saturation in said hemoglobin provides an early indication of respiratory stress.

14. The device according to claim 13 wherein said respiratory stress is associated with Sudden Infant Death Syndrome.

15. The device according to claim 1 further produces an output signal sent by said processor to an alarm unit for alerting when said at least one blood constituent level falls outside of a predetermined range.

16. The device according to claim 13 used to monitor the heart rate.

17. The device according to claim 13 used as an apnea monitor.

18. The device according to claim 13 wherein the device is a portable hand held reflective pulse oximeter.

19. The device according to claim 1 adapted to determine blood billirubin levels.

20. The device according to claim 1 used for mapping the intensity of said AC signal along the surface of said organ to detect regions of said organ having a reduced blood flow.

21. A method for non-invasive measurement of a level of at least one blood constituent, the method comprising the steps of:

providing light from at least one light source disposed proximate the skin, directing said light toward the skin surface, said light being reflected from said skin;

providing a light detector spaced apart from said at least one light source and being sensitive to intensity levels of said light reflected from said skin for producing intensity signals in accordance therewith; and

processing said intensity signals received from said light detector, said processing step comprising the steps of:

amplifying said intensity signals in first and second amplifiers, each in accordance with a respective first and second gain amplification factor; and

automatically determining said first and second gain amplification factors in adjustable fashion;

wherein during a first stage, said first and second amplifier amplify a DC signal component of said intensity signals in accordance with predetermined first and second gain amplification factors, said DC signal component being subtracted from said intensity signals at an input of said first amplifier, thereby isolating an AC signal component of said intensity signals,

and wherein during a second stage, said second amplifier amplifies said isolated AC signal component in accordance with said adjustably-determined second gain amplification factor,

said processing step producing output signals in accordance with said isolated AC signal component and said DC signal component; and

calculating in accordance therewith, said at least one blood constituent level.

22. The method according to claim 21 further comprising the step of transmitting said output signals to a receiver at a remote location, allowing monitoring of said at least one blood constituent level from said remote location,

said receiver being equipped with an alarm unit for alerting when said at least one blood constituent level falls outside of a predetermined range.

23. The method according to claim 21 wherein said step of processing further comprises:

normalizing said AC and DC output signal components to produce first and second normalized signals;

forming a ratio of said first and second normalized signals; and

calculating said blood constituent level in accordance with said ratio.

24. The method according to claim 21 further comprising the steps of:

developing a control signal when said adjustably-determined second gain amplification factor is established in said second stage; and

shutting off said at least one light source in response to said control signal.

25. The method according to claim 21 further comprising the steps of:

determining said first and second gain amplification factors by a processor in an iterative process by adjustably setting a gain amplification factor; and

measuring a dynamic voltage range of said output signals to determine if said voltage range falls within a predetermined window established by said processor.

26. The method according to claim 21 wherein said blood constituent is hemoglobin, the method further comprising the step of measuring a level of oxygen saturation in said hemoglobin providing an early indication of respiratory stress.

27. The method according to claim 26 wherein said respiratory stress is associated with Sudden Infant Death Syndrome.

28. The method according to claim 21 further comprising the step of initiating an alarm for alerting when said at least one blood constituent level falls outside of a predetermined range.

29. The method according to claim 28 wherein said alarm is selected from an audible alarm, a visual alarm, a tactile alarm, dialing a telephone number and any combination thereof.

30. The method according to claim 21 wherein said light is alternatingly selected from at least a first wavelength range and a second wavelength range, said first wavelength range being at least partially different from said second wavelength range.

31. The method according to claim 30 wherein said first wavelength range includes wavelength of red light and said second wavelength range includes wavelength of infra-red light, said at least one blood constituent is hemoglobin and wherein said method determines the level of oxygen saturation of said hemoglobin.

32. The method according to claim 31 used for monitoring the heart rate.

33. The method according to claim 31 used for monitoring a condition of apnea.

34. The method according to claim 21 used for monitoring the level of billirubin in blood.

35. The method according to claim 31 further including the step of repeating said steps of providing light, providing a light detector and processing, at a plurality of positions along said skin for mapping the levels of said AC signal component along the surface of said skin to detect regions of reduced blood flow.

36. A method for measurement of a level of at least one blood constituent, the method comprising the steps of:

providing light from at least one light source disposed proximate the surface of an organ, directing said light toward the surface of said organ, said light being reflected from said organ;

providing a light detector spaced apart from said at least one light source and being sensitive to intensity levels of said light reflected from said organ for producing intensity signals in accordance therewith; and

processing said intensity signals received from said light detector, said processing step comprising the steps of:

amplifying said intensity signals in first and second amplifiers, each in accordance with a respective first and second gain amplification factor; and

automatically determining said first and second gain amplification factors in adjustable fashion;

wherein during a first stage, said first and second amplifier amplify a DC signal component of said intensity signals in accordance with predetermined first and second gain amplification factors, said DC signal component being subtracted from said intensity signals at an input of said first amplifier, thereby isolating an AC signal component of said intensity signals,

and wherein during a second stage, said second amplifier amplifies said isolated AC signal component in accordance with said adjustably-determined second gain amplification factor,

said processing step producing output signals in accordance with said isolated AC signal component and said DC signal component; and

calculating in accordance therewith, said at least one blood constituent level.

37. The method according to claim 36 wherein said organ is an internal organ and wherein said method further includes the step of repeating said steps of providing light, providing a light detector and processing, at a plurality of positions along the surface of said internal organ for mapping the levels of said AC signal component along the surface of said internal organ to detect regions of reduced blood flow.

38. A method for non-invasively determining the blood flow velocity in a region of an organ, the method comprising the steps of:

positioning a first pulse-oximetry device and a second pulse-oximetry device proximate the surface of said region, said first and said second device being separated from each other by a predetermined distance;

simultaneously obtaining a first and a second sets of data representing the pulsatile variation of the level of oxygen saturation at the locations of said first and said second device, respectively, as a function of time, each of said first set and second set of data including at least one extremum data value, said at least one extremum data value of said first set of data corresponding to said at least one extremum data value of said second set of data;

calculating the time interval between said at least one extremum data value of said first set of data and said at least one extremum data value of said second set of data;

dividing the value of said predetermined distance by the value of said time interval to obtain a value representing the approximate blood flow velocity in said region of said organ,

wherein each of said first device and said second device includes:

at least one light source, providing light directed toward the surface of said organ, said light being reflected from said organ;

a light detector spaced apart from said at least one light source and being sensitive to intensity levels of said reflected light for producing intensity signals in accordance therewith; and

a processing unit for processing said intensity signals received from said light detector, said processing unit comprising:

first and second amplifiers for amplifying said intensity signals, each in accordance with a respective first and second gain amplification factor; and

a processor for automatically determining said first and second gain amplification factors in adjustable fashion;

wherein during a first stage, said first and second amplifiers amplify a DC signal component of said intensity signals in accordance with predetermined first and second gain amplification factors, said amplified DC signal component being subtracted from said intensity signals at an input of said first amplifier, to isolate an AC signal component of said intensity signals,

and wherein during a second stage, said second amplifier amplifies said isolated AC signal component in accordance with said adjustably-determined second gain amplification factor,

said processing unit producing output signals in accordance with said isolated AC signal component and said DC signal component and calculating in accordance therewith, said level of oxygen saturation.

39. The method according to claim 38 wherein said organ is the skin.

40. The method according to claim 38 wherein said at least one extremum data value is selected from a minimum data value and a maximum data value.

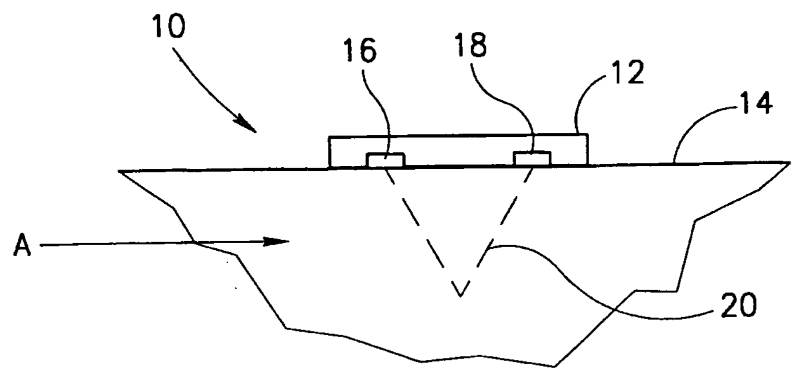

FIG.1

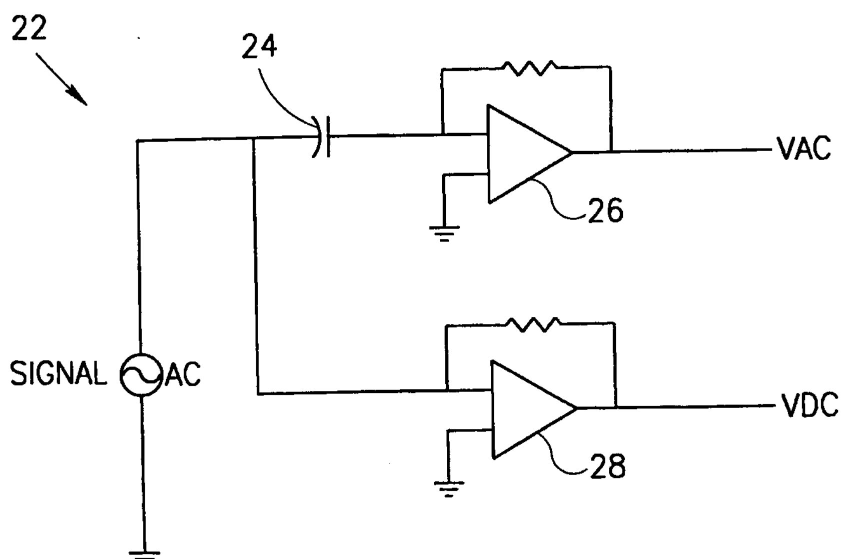

FIG.2
PRIOR ART

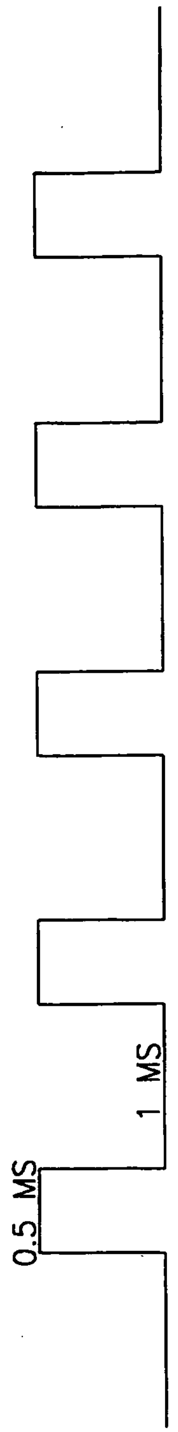

FIG.3A

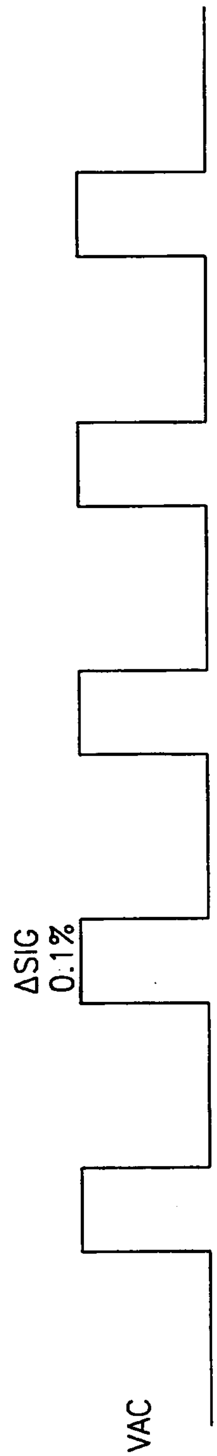

FIG.3B
PRIOR ART

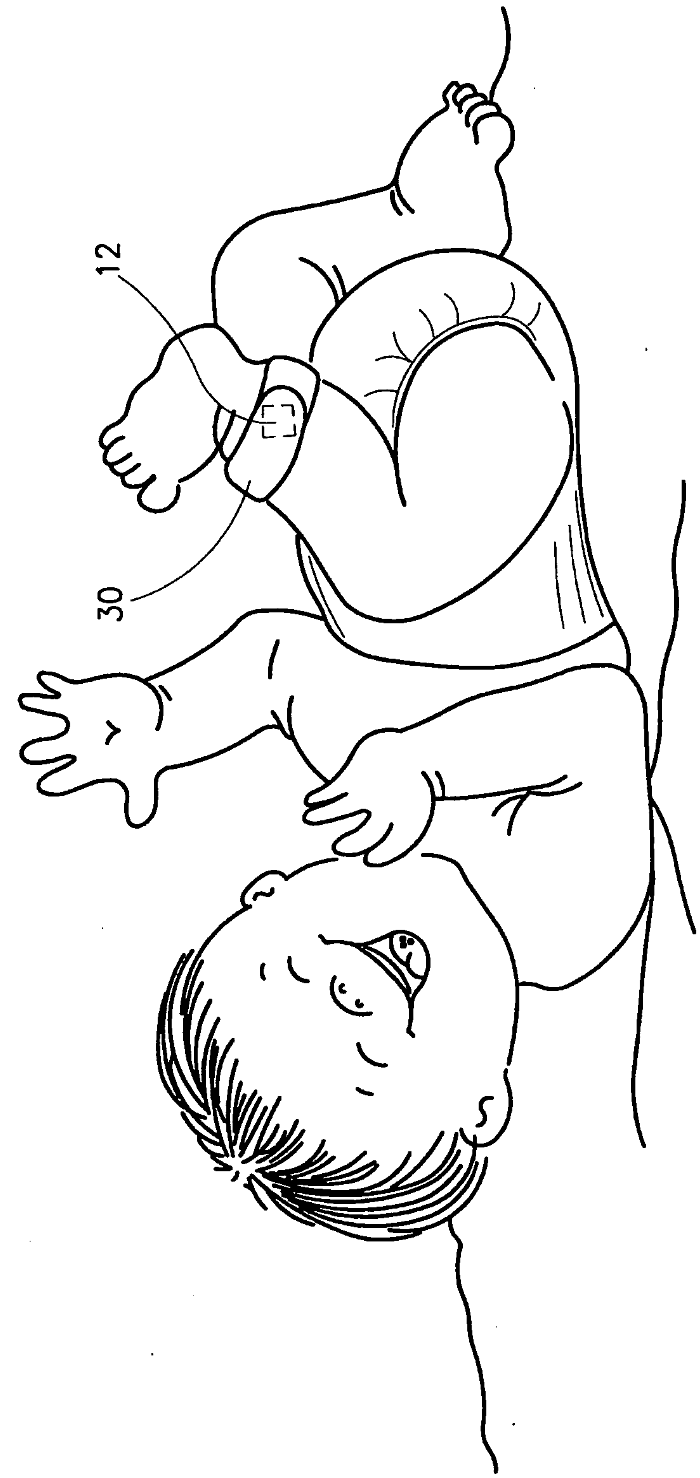

FIG.4

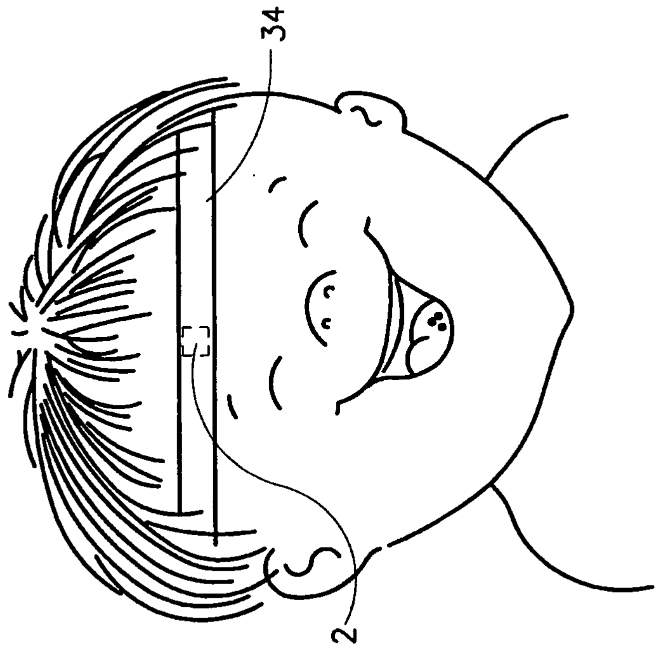

FIG.5B

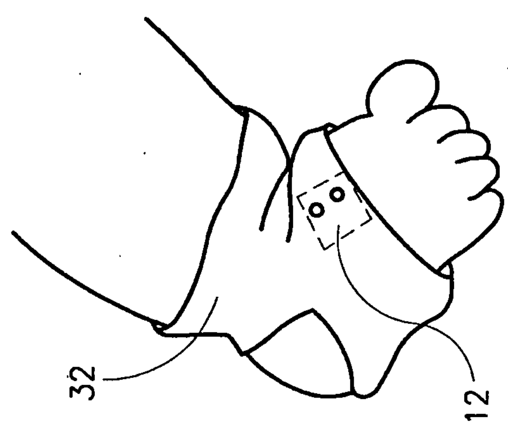

FIG.5A

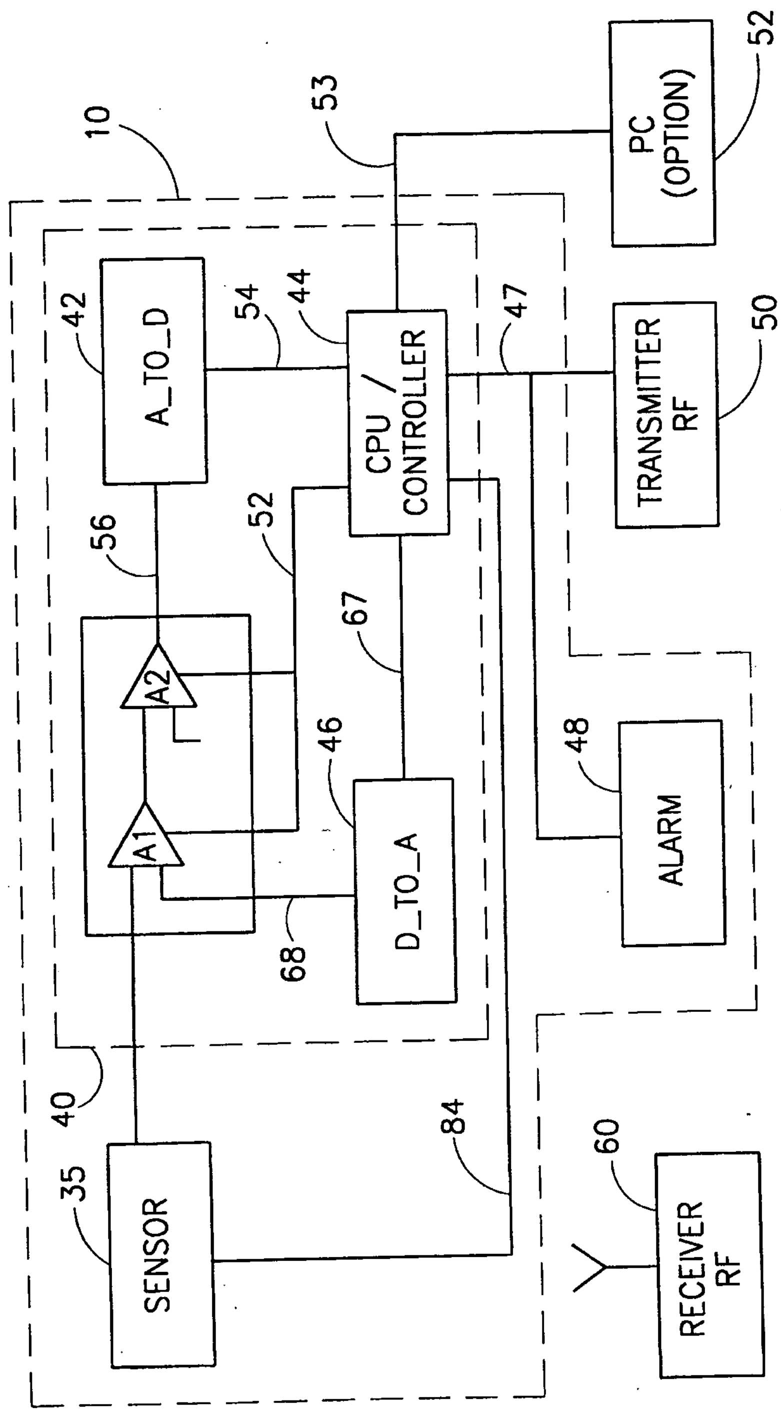
10
53
52
PC
(OPTION)
42
A_TO_D
54
44
CPU /
CONTROLLER
47
TRANSMITTER
RF
50
56
52
67
A2
A1
46
D_TO_A
68
48
ALARM
40
84
35
SENSOR
60
RECEIVER
RF

FIG.6

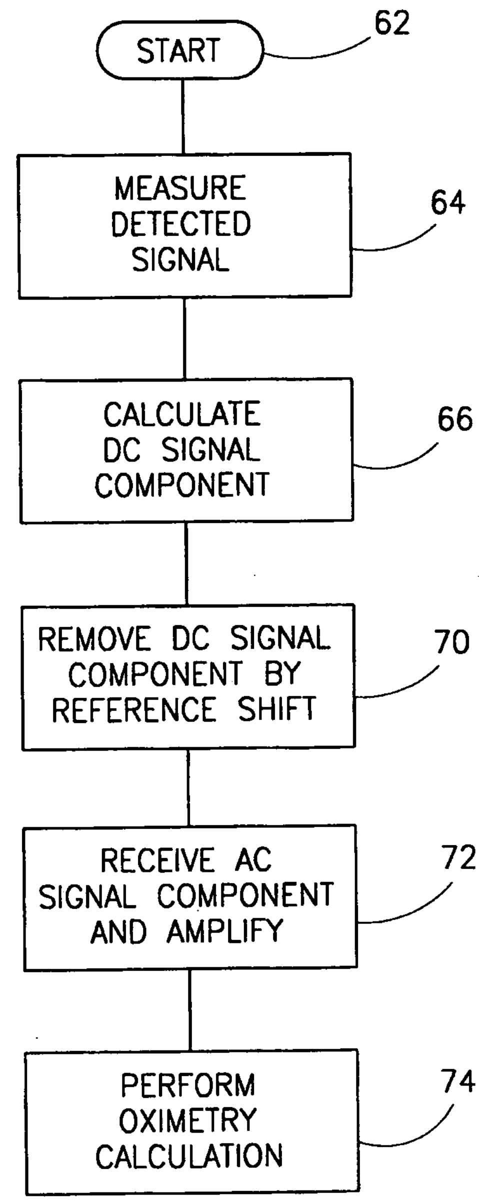
START
62
MEASURE DETECTED SIGNAL
64
CALCULATE DC SIGNAL COMPONENT
66
REMOVE DC SIGNAL COMPONENT BY REFERENCE SHIFT
70
RECEIVE AC SIGNAL COMPONENT AND AMPLIFY
72
PERFORM OXIMETRY CALCULATION
74

FIG.7

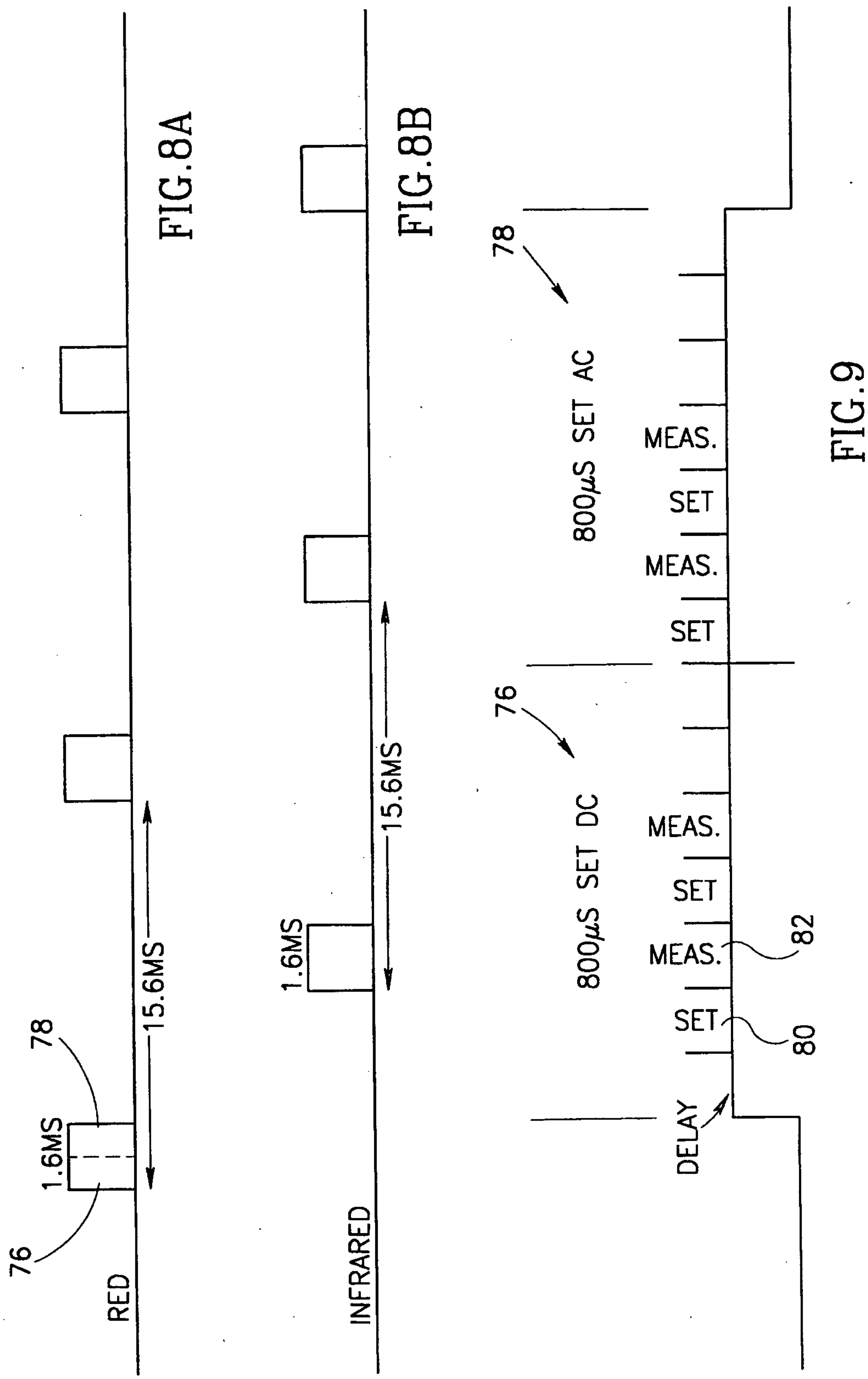

FIG.8A

FIG.8B

FIG.9

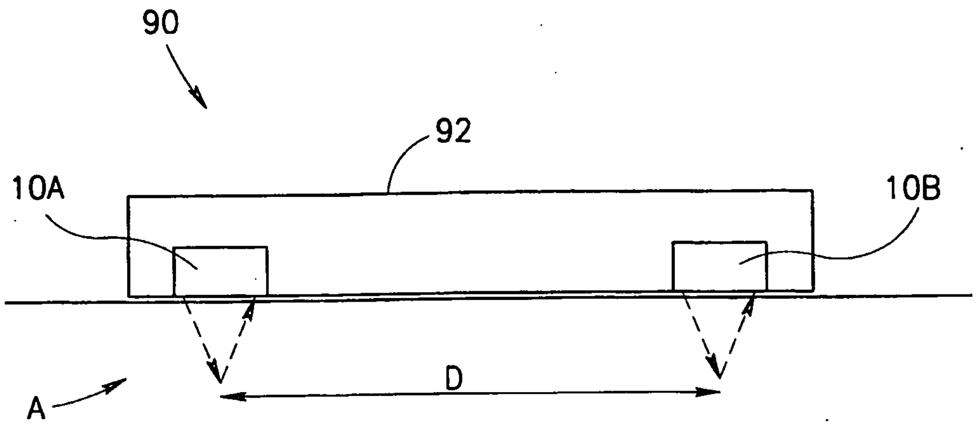

FIG.10

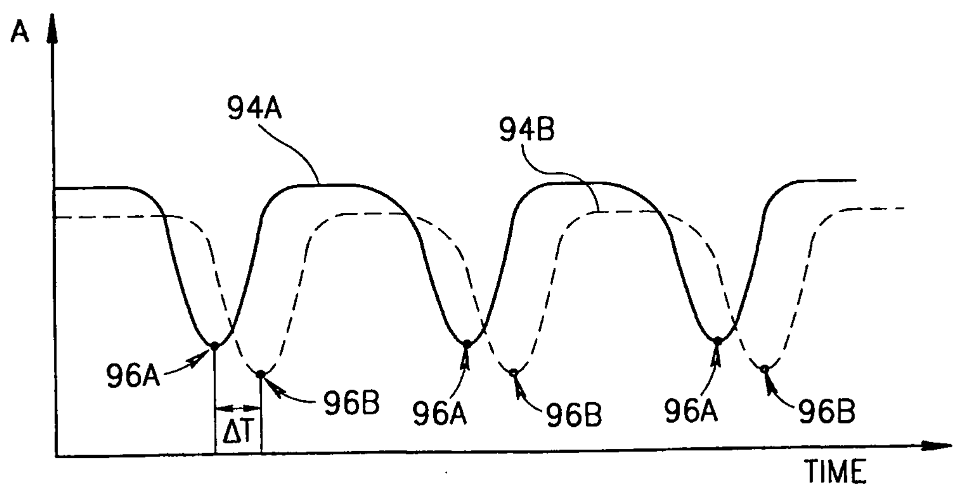

FIG.11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL98/00270

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 5/00
US CL :600/322
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/322-324, 326, 330, 479

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,351,685 A (POTRATZ) 04 October 1994, col. 2 line 45 to col. 3 line 30; col. 6 line 29 to col. 7 line 3, col. 8 line 20 to col. 9 line 6.	1, 2, 4, 5, 10-13, 15, 16, 18, 21, 26, 28-32, 36 --- 3, 6, 9, 14, 17, 22, 23, 25, 27, 33
Y	US 5,515,858 A (MYLLYMAKI) 14 May 1996, the entire document.	6, 22
Y	US 4,765,340 A (SAKAI et al) 23 August 1988, col. 1 lines 21-42.	14, 17, 27, 33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search 25 AUGUST 1998	Date of mailing of the international search report 13 OCT 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ERIC F. WINAKUR Telephone No. (703) 308-39940

Form PCT/ISA/210 (second sheet)(July 1992)★